

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM) NOTICE OF AMENDMENT
37.57.301, 37.57.304, 37.57.305,)
37.57.306, 37.57.307, 37.57.308,)
37.57.315, 37.57.316, 37.57.320, and)
37.57.321 pertaining to newborn)
screening tests and eye treatment)

TO: All Interested Persons

1. On November 8, 2007, the Department of Public Health and Human Services published MAR Notice No. 37-422 pertaining to the public hearing on the proposed amendment of the above-stated rules, at page 1790 of the 2007 Montana Administrative Register, issue number 21.

2. The department has amended ARM 37.57.306, 37.57.307, 37.57.308, 37.57.315, 37.57.320, and 37.57.321 as proposed.

3. The department has amended the following rules as proposed with the following changes from the original proposal. New matter to be added is underlined. Matter to be deleted is interlined.

37.57.301 DEFINITIONS As used in this subchapter, the following definitions apply:

(1) and (2) remain as proposed.

(3) "Newborn screening tests" are laboratory screening tests for the following conditions:

(a) Acylcarnitine Disorders:

(i) Fatty Acid Oxidation Disorders:

(A) ~~Carnitine~~ Carnitine uptake defect;

(B) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency;

(C) Medium-chain acyl-CoA dehydrogenase deficiency;

(D) Trifunctional protein deficiency; and

(E) Very long-chain acyl-CoA dehydrogenase deficiency;

(ii) Organic Acidemia Disorders:

(A) ~~3-OH-3-CH3 glutaric aciduria~~ 3-hydroxy-3-methylglutaryl-CoA lyase deficiency;

(B) ~~3-m~~ Methylcrotonyl-CoA carboxylase deficiency;

(C) β -ketothiolase deficiency;

(D) Glutaric acidemia type I;

(E) Isovaleric acidemia;

(F) Methylmalonic acidemia (Cbl A,B);

(G) Methylmalonic acidemia (mutase deficiency);

(H) Multiple carboxylase deficiency; and

- (l) Propionic acidemia;
- (b) Amino Acid Disorders:
 - (i) Argininosuccinic acidemia;
 - (ii) Citrullinemia;
 - (iii) Homocystinuria (~~due to CBS deficiency~~);
 - (iv) Maple syrup urine disease;
 - (v) Phenylketonuria; and
 - (vi) Tyrosinemia type I;
- (c) Biotinidase deficiency;
- (d) Classical galactosemia;
- (e) Congenital adrenal hyperplasia (~~21-hydroxylase deficiency~~);
- (f) Congenital hypothyroidism;
- (g) Cystic fibrosis; and
- (h) Hemoglobinopathies, including:
 - (i) Hb S/ $\beta\beta$ -thalassemia;
 - (ii) Hb SC disease; and
 - (iii) Hb SS disease (~~Sickle cell anemia Hb~~).

AUTH: 50-19-202, MCA

IMP: 50-19-203, MCA

37.57.304 VERY LOW BIRTH WEIGHT (UNDER 1,500 GRAMS)

NEWBORNS (1) remains as proposed.

~~(2) If the infant is not yet feeding when the initial screening sample is collected, a repeat specimen for phenylalanine testing must be taken at least 48 hours following the first ingestion of milk.~~

~~(3)~~ (2) In the event that the newborn stays in a health care facility longer than 14 days following birth, a repeat congenital hypothyroid screening must be made either at the time of discharge if the stay is less than one month, or at one month of age if the stay is one month or longer.

AUTH: 50-19-202, MCA

IMP: 50-19-203, MCA

37.57.305 NEWBORNS OTHER THAN THOSE WITH VERY LOW BIRTH WEIGHT (1) For newborns at birth weights of 1,500 grams or more, the required blood specimen must be taken:

~~(a) between 24 and 72 hours of age; or,~~

~~(b) 48 hours following its first ingestion of milk, but not later than the seventh day of life.~~

(2) through (3) remain as proposed.

AUTH: 50-19-202, MCA

IMP: 50-19-203, MCA

37.57.316 ABNORMAL TEST RESULT (1) and (1)(a) remain as proposed.

(b) the person to whom the above report is made must ensure that within 48

hours of receiving the notification of an abnormal test result, a second blood specimen ~~is will be~~ taken ~~within 24 hours of notification~~ and submitted to the department for a second test.

(2) through (3) remain as proposed.

AUTH: 50-19-202, MCA

IMP: 50-19-203, MCA

4. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

COMMENT #1: The department received two formal comments which asked the department to amend the proposed rules to remove the list of specific conditions for which the proposed rules require mandatory screening. Instead, the persons providing the comments proposed that the rules make a general statement requiring that the hospitals and other facilities conduct screening with an expanded panel of tests as "recommended by" the American Academy of Pediatrics (AAP) or other appropriate organization. The comments indicated that newborn screening is an ever changing field and that it would be more efficient to have a general requirement so that as the recommendations of the AAP change and as new and accepted tests become available, it will not be necessary to amend the rules in the future.

RESPONSE: In order to enforce a mandatory newborn screening requirement, the screening requirement must be sufficiently specific to put the hospital or other facility charged with providing the screening on notice of what it is being required to do. The department has set out the specific recommendations made by the AAP in March of 2005. That listing was presented to the 2007 Legislature as the then most current standard for newborn screening and was used to support an appropriation for Medicaid reimbursement for providers conducting screening for these conditions on a patient who is Medicaid eligible. The department recognizes that recommendations of the AAP likely will change over time as effective screenings for other conditions are developed. However, the department cannot require a hospital or facility to conduct screening for such other conditions unless they are specifically identified in the administrative rules. Additionally, the department does not want to require that a health care provider conduct a screening test on a Medicaid patient if that test is not Medicaid reimbursable. The department therefore anticipates that future amendments to this rule will likely occur. When that occurs, a request will also be made to the Legislature for an appropriation that will allow Medicaid reimbursement for any new screening tests required that are performed on Medicaid eligible patients. In the interim, however, any hospital or other facility conducting newborn screenings may certainly choose to also conduct screenings for other conditions as recommended by the AAP.

COMMENT #2: A suggestion was made that ARM 37.57.304(2) and 37.57.305(1)(b) be omitted to reflect the advances in Phenylketonuria (PKU) screening. Those current provisions both require that blood samples taken for PKU screening occur at least 48 hours after the newborn has first ingested milk.

RESPONSE: This recommendation has been reviewed by the Montana Public Health Laboratory and the department agrees with this comment. The department has determined that it would be appropriate to delete ARM 37.57.304(2) and 37.57.305(1)(b) because current testing methodology for PKU is not sensitive to infant feeding status. The department will therefore delete ARM 37.57.304(2) and 37.57.305(1)(b).

COMMENT #3: A question was raised about whether out-of-state hospitals are bound by Montana's Administrative Rules in terms of newborn screening requirements for babies born in Montana and transferred to hospitals in other states.

RESPONSE: ARM 37.57.306 and all other rules in the Administrative Rules of Montana apply only to Montana institutions. The state of Montana does not have legal authority over institutions in other states. The department will therefore make no change to this rule.

COMMENT #4: One comment requested that additional time be provided for hospitals and other facilities conducting newborn screening to allow up to 48 hours to obtain a specimen for a follow-up testing after an abnormal test result is received, instead of requiring that the specimen be taken within 24 hours after receiving such notification. The commentor noted that it sometimes takes longer than 24 hours to find the family and to talk to the specialist, who may order a different test after an initial abnormal test result, rather than repeating the same test.

RESPONSE: After reviewing this comment and recommendation, the department agrees. It will change ARM 37.57.316(1)(b) to read: "(b) the person to whom the above report is made must ensure that within 48 hours of receiving notification of an abnormal test result, a second blood specimen will be taken and submitted to the department for a second test".

COMMENT #5: One recommendation was made that the listing of screening tests in ARM 37.57.301 be simplified to list the categories of disease conditions for which screening will be mandatory, rather than each specific disease condition.

RESPONSE: The department has considered this recommendation, but rejects it. The originally published list of disease conditions for which a newborn must be screened is adopted with only minor spelling and typographical changes. It identifies general categories of diseases and then the specific disease conditions within those categories for which newborns must be screened. The department has decided to modify the listings to reflect the conditions for which screening will be performed, instead of the names of the specific defect involved.

COMMENT #6: The proposed rules require that the initial newborn screening blood specimen be taken after 24 hours of birth. For a very low birth weight baby, the test must be taken no later than seven days of age unless medically contraindicated. For other babies, the sample must be taken between 24 and 72 hours of age. A comment was received requesting that the department change this requirement to

allow an additional day for that test for babies who do not have low birth weight. The comment pertained to the situation in which the newborn is delivered at home and where it may take several days before the mother is ready to come into town due to recovery issues or travel limitations due to the weather and where the health care provider attending the birth may have difficulty returning to the home within three days due to weather problems or because of the need to attend other births.

RESPONSE: The department does not support the recommended change to increase the maximum time period in this rule. The department considers it of critical importance that there is no longer delay for taking an initial screening sample for any baby, whether born in or outside of a hospital.

COMMENT #7: One commentor expressed concern about how to handle parental refusal of the mandatory newborn bloodspot screening.

RESPONSE: The administrative rules regulate the activities of those professional individuals who attend births in Montana. The rules require those professionals to cause the bloodspot specimen to be taken and submitted to the department. It would be the department's recommendation that a professional who offers a screening to a parent who refuses it document the parent refusal as part of the baby's medical record in order to establish that the screening was offered and refused.

COMMENT #8: A question was received about whether provisions have been made for parents who cannot afford the increased cost of the expanded screening.

RESPONSE: The 2007 Montana Legislature increased state matching funds for Medicaid to cover potential increased Medicaid costs for the additional newborn screening for Medicaid eligible patients.

/s/ Kimberly Kradolfer
Rule Reviewer

/s/ Joan Miles
Director, Public Health and
Human Services

Certified to the Secretary of State January 7, 2008.